



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,050	11/25/2003	David H. Deaton	DEA9902DV	7773

25197 7590 12/07/2006

LEARY & ASSOCIATES
3900 NEWPARK MALL RD.
THIRD FLOOR, SUITE 317
NEWARK, CA 94560

EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
----------	--------------

3738

DATE MAILED: 12/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/723,050

Applicant(s)

DEATON, DAVID H.

Examiner

Paul B. Prebilic

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 21-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 25, 2006 has been entered.

Claim Objections

Claims 4, 16, 24, and 28 are objected to because of the following informalities:

With regard to claims 4 and 16, on line 2 of each claim, the language pertaining to the slits is not clear. The Examiner suggests inserting "the longitudinal axis of the" after "with respect to the" in order to make the claim language clearer.

With respect to claims 24 and 28, line 2 of each, "the fenestrated endovascular graft" lacks antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 appears to contradict base claim 10 that states that the "inner tubular graft body sized and configured for placement with the central lumen

Art Unit: 3738

of the outer tubular graft body.” (emphasis added) If the attachment is permanent as in claim 13, than it is unclear how the inner graft body can be for placement with the outer tubular graft body.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6, 8, 9, and 23-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Shmulewitz (US 5,961,548) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shmulewitz (US 5,961,548) in view of Reydel (US 6,589,213) or Millar (US 4,966,148) or Solar (US 5,549,119). Shmulewitz anticipates the claim language where the tubular graft as claimed is the main portion (12) of Shmulewitz (see Figure 1), the fenestrations as claimed are the perforations (see Figure 3A and column 4, lines 14-35), the catheter as claimed is catheter (40) (see Figures 6A to 6C and column 5, lines 1-67), the guidewire as claimed is guidewire (65), and the piercing element on the guidewire as claimed is the nose cone (49); see column 5, lines 24-29. The nose cone is viewed as being attached to the guidewire to the extent required by the claim language.

Alternatively, one could interpret the claim language as the Applicant has, such that the piercing element is fixedly attached to the guidewire. Shmulewitz teaches a slidable attachment instead. However, Reydel (see the abstract, figures, particularly Figures 15 and 16) or Millar (see column 8, lines 14-38, particularly lines 33-35) or Solar (see the figures and column 3 and 4, particularly elements (28) and (58)) each teach that it was known to fixedly attach other devices to guidewires as needed. Therefore, it is the Examiner's position that it would have been obvious to fixedly attach the nose cone of Shmulewitz to the guidewire as shown or to a different guidewire in the manner shown so that the nose cone would not have to be separately forced through the fenestrations. This would simplify the process of opening the hole.

With regard to claim 8, the Examiner asserts that "rearward facing" does not distinguish the guidewire claimed from that of Shmulewitz because rearward is a direction that has no orientation with respect to anything else. Likewise, proximal and distal ends of Shmulewitz can be either end of the guidewire (65) and does not necessitate that the distal end be the one shown piercing the graft of Shmulewitz.

Regarding claim 25, the relative stiffness is not compared to any known value or to the rest of the guidewire, and for this reason, it can be of any stiffness.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shmulewitz (US 5,961,548) in view of Wisselink (US 5,984,955). Shmulewitz meets the claim language as explained *supra* but fails to disclose the use of a grommet or flange for the sidebranch graft attachment as claimed. However, Wisselink teaches that it was known to use grommets and flanges with similar such grafts as a means to securely attach the side graft with the main graft; see the figures and column 3, line 35+. Therefore, it is the Examiner's position that it would have been obvious to use a grommet or flange with the Shmulewitz side graft for the same reasons that Wisselink uses the same or to securely attach the two grafts together.

Claims 10-16, 18, 21, 22, and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dereume et al (US 5,723,004) in view of Shmulewitz (US 5,961,548) or, in the alternative, as obvious over Shmulewitz (US 5,961,548) in further view of Reydel (US 6,589,213) or Millar (US 4,966,148) or Solar (US 5,549,119).

Dereume meets the claim language except for clearly disclosing a guidewire that is capable of forming an opening in the graft wall as claimed; see Figures 3, 4, and 9-13 as well as columns 4 to 6. However, Shmulewitz teaches that it was known to make guidewires capable of forming openings in similar grafts where the nose cone is attached to the guidewire as claimed; see the previously cited portions *supra*. Therefore, it is the Examiner's position that it would have been obvious to include a guidewire in the Dereume invention that is capable of forming openings in the graft wall for the same reasons that Shmulewitz includes the same or to make the openings optional to the user.

Alternatively, one could interpret the claim language as the Applicant has, such that the piercing element is fixedly attached to the guidewire. Shmulewitz teaches a slidable attachment instead. However, Reydel (see the abstract, figures, particularly Figures 15 and 16) or Millar (see column 8, lines 14-38, particularly lines 33-35) or Solar (see the figures and column 3 and 4, particularly elements (28) and (58)) each teach that it was known to fixedly attach other devices to guidewires as needed. Therefore, it is the Examiner's position that it would have been obvious to fixedly attach the nose cone of Shmulewitz to the guidewire as shown or to a different guidewire in the manner shown so that the nose cone would not have to be separately forced through the fenestrations. This would simplify the process of forming the hole.

With regard to claim 14, the grafts of Dereume are considered separable to the extent that this language can be given patentable weight because one could at least cut them apart.

With regard to claims 15 and 16, Dereume fails to disclose fenestrations in the form of slits in two different orientations. However, Shmulewitz teaches that it was known to make fenestrations as perforations so that they can be expanded to the extent desired. Therefore, it is the Examiner's position that it would have been obvious to make the openings (37) of Dereume in the form of expandable slits for the same reasons that Shmulewitz does the same.

With regard to claim 18, Dereume fails to disclose a side branch graft therewith. However, Shmulewitz teaches that it was known to use such in similar devices. Therefore, it would have been obvious to use a side branch graft in order to better direct

the blood flow and to prevent blood and blood pressure from being exposed to the diseased vessel wall.

Claims 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dereume, Shmulewitz, Reydel, Millar, and Solar as applied to claims 10-16, 18, 21, 22, and 27-30 above, and further in view of Wisselink (US 5,984,955). Dereume as modified by Shmulewitz fails to teach the concept of using grommets or flanges to attach side grafts to main grafts as claimed. However, Wisselink teaches that it was known to use grommets and flanges with similar such grafts as means to securely attach the side graft with the main graft; see the figures and column 3, line 35+. Therefore, it is the Examiner's position that it would have been obvious to use a grommet or flange with the Shmulewitz modified Dereume side graft for the same reasons that Wisselink uses the same or to more securely attach the two grafts together.

Response to Arguments

Applicant's arguments filed September 25, 2006 have been fully considered but they are not persuasive. On page 7 of the response, the Applicant argues that there is no piercing element on or attached to the guidewire in Shmulewitz. The Examiner respectfully disagrees. The piercing element is the nose cone (49) and it is clearly on the guidewire (65) and it is slidably attached thereto; see Figures 6C. For this reason, the rejections have been maintained. Furthermore, an alternative Section 103 rejection has been added to address Applicant's understanding of the claim language.

With regard to the traversal of the other rejections, these traversals basically rely on the Applicant's interpretation of the language "attached to." Since this issue was addressed in both the rejections and in the previous paragraph, there is no need of a further response.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
Art Unit 3738